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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/718,500

11/19/2003

Jim E. Leone

MICRU-65282

8234

24201 7590 02/25/2008  
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EXAMINER

MENDOZA, MICHAEL G

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

02/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/718,500	<b>Applicant(s)</b> LEONE ET AL.	
	<b>Examiner</b> MICHAEL G. MENDOZA	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 1/7/2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,6-19,21-30,34,35,37,39,40 and 44-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,6-19,21-30,34,35,37,39,40 and 44-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/7/2005 has been entered.

### ***Response to Arguments***

2. Applicant's arguments filed 12/10/2007 have been fully considered but they are not persuasive. The applicant has amendment the independent claims to include the limitation of an inner reinforcement member. The prior art reference to Ferrera et al. is capable of reading on the limitation. The device of Ferrera et al. comprises an inner member 14 within strand 10 as seen in figs. 4 and 5. The 35 U.S.C. 102(b) to Ferrera et al. is maintained.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3, 6-19, 21-30, 34, 35, 37, 39, and 40, and 44-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In claims 1, 17, and 40, the Applicant is required to clarify to what the claim is intended to be drawn to, i.e., either the vasoocclusive device alone or the combination of the vasoocclusive device and the pusher. The Applicant sets forth the combination of the vasoocclusive device and the pusher when describing the how the vasoocclusive device is mounted in the body of the claims, which is inconsistent with preamble, that sets forth the subcombination of vasoocclusive device. Applicant is required to make the language of the claims consistent with the intent of the claims. It should also be noted that in considering the claims on the merits, the Examiner will consider the claims as drawn to the combination.

6. Claim 35 recites the limitation "the formed flexible material" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3, 6-19, 21-30, 34, 37, 39, 40, and 44-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferrera et al. 6171326.

Ferrera et al. teach a vasoocclusive device comprising: at least one strand of a flexible material having a distal end and a proximal end, the at least one strand being formed to have a first inoperable, substantially linear configuration for insertion into and through a

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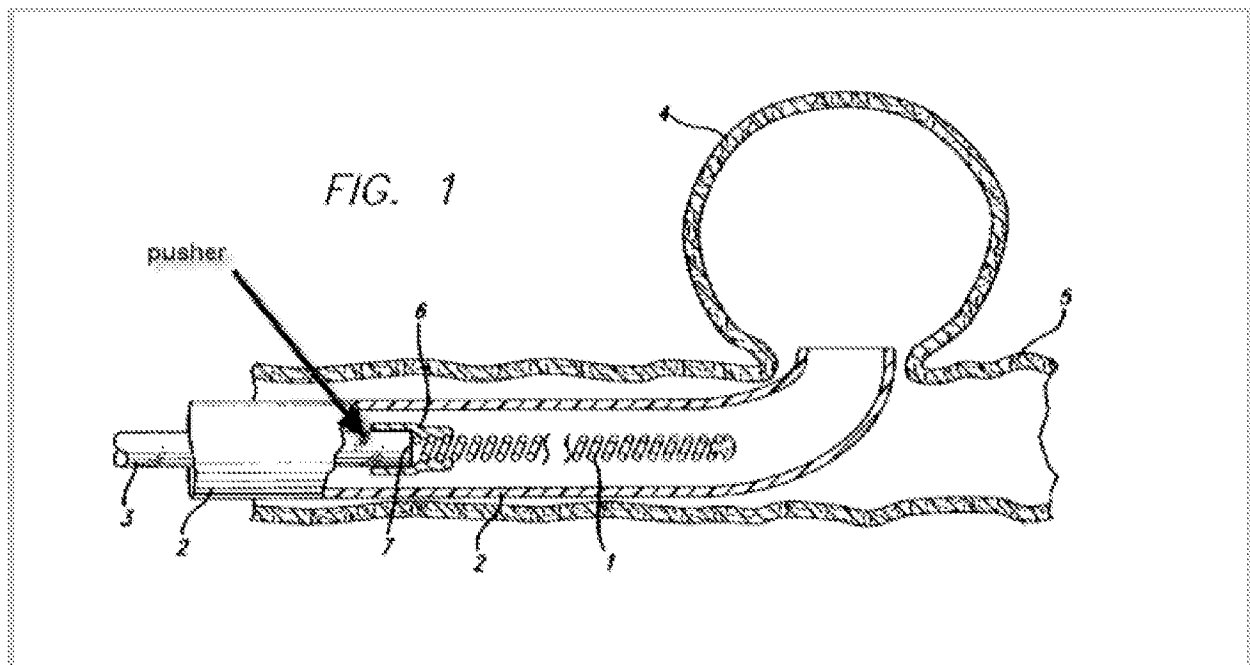
catheter to a desired portion of the vasculature to be treated, and a second operable configuration for framing or occluding the desired part of the vasculature to be treated, said operable configuration including a first portion at the distal end configured to frame or occlude a part of the vasculature to be treated and a second non linear portion at the proximal end configured to engage an artery wall for securing the occluding device in the artery system of the vasculature; and an inner reinforcement member extending through the first portion and the anchor portion to reinforce the anchor portion, the inner reinforcement member having a distal end fixedly attached to the distal end of that at least one strand, and the inner reinforcement member having a proximal end detachably mounted to the pusher member; wherein the portion for securing the occluding device in an artery system of the vasculature comprises an anchor portion of the second operable configuration to secure the occluding portion of the device in the artery system of the vasculature; wherein the anchor portion comprises a plurality of extending loops along a longitudinal axis to thereby provide contact surface area for anchoring the occluding portion of the device in the artery system of the vasculature; a second portion having a first inoperable, substantially linear configuration for insertion into and through a catheter to a desired portion of the vasculature to be treated, and a second operable, coiled shape for filling and reinforcing the desired portion of the vasculature when the vasoocclusive device is implanted at the site in the vasculature to be treated; a second portion having a first inoperable, substantially linear configuration for insertion into and through a catheter to a desired portion of the vasculature to be treated, and a second operable, substantially helical coil shape for filling and reinforcing

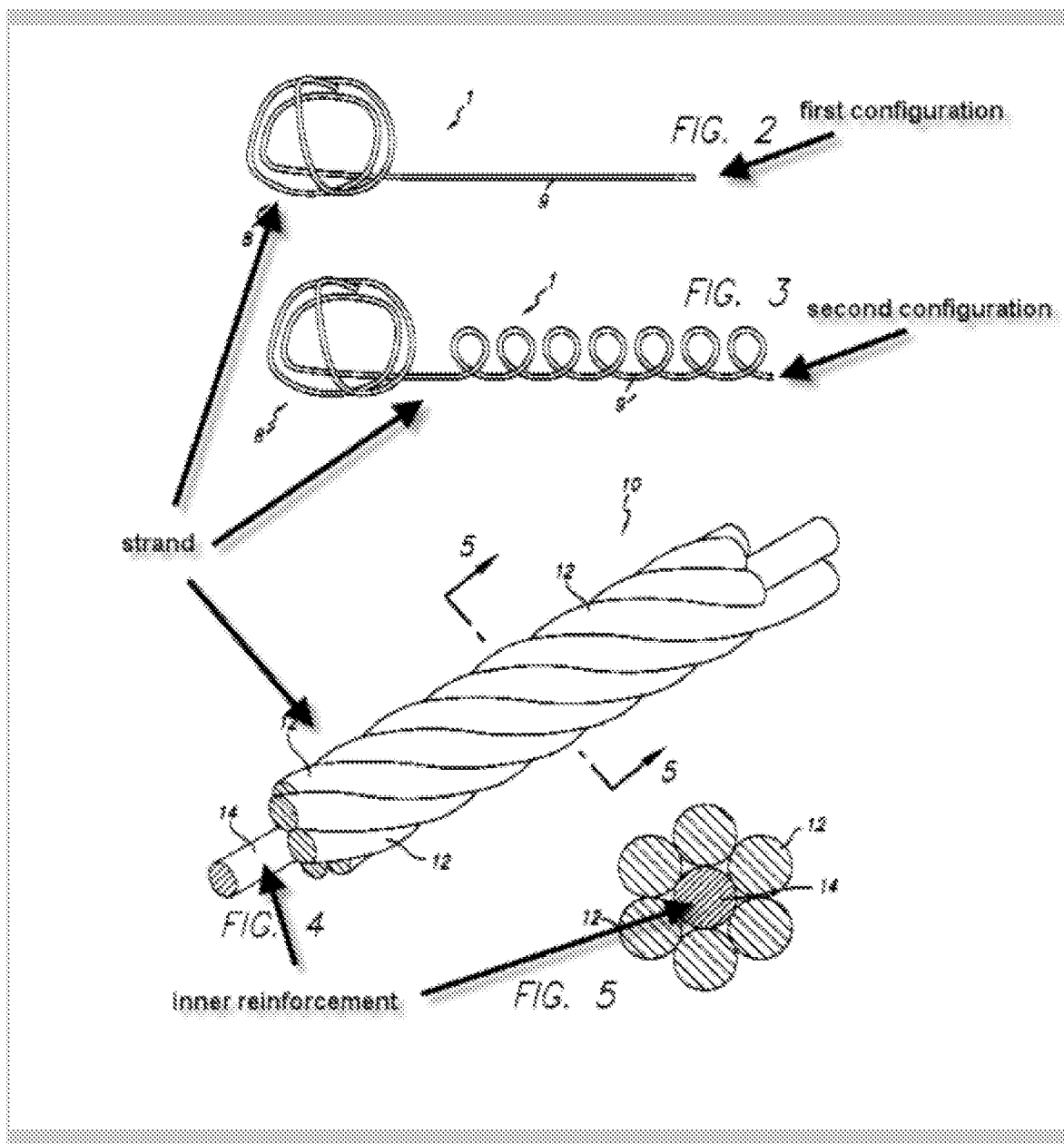
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the desired portion of the vasculature when the vasoocclusive device is implanted at the site in the vasculature to be treated; wherein said at least one strand of a flexible material is a helical shape; wherein said at least one strand of a flexible material is a wire (see figures); wherein said flexible material comprises an alloy of titanium and nickel (col. 6, lines 59-60); wherein said flexible material comprises a metal selected from the group consisting of platinum, palladium, rhodium, gold, tungsten, and alloys thereof (col. 6, lines 65-67); wherein said vasoocclusive device is formed from at least one flexible strand of a resilient radiopaque material to provide a radiopaque marker of the deployed configuration of a device made of the strand during vascular surgery; wherein said radiopaque strand comprises an alloy selected from the group consisting of platinum, tungsten and gold (col. 6, line 65-67); wherein said at least one strand comprises a super-elastic material; wherein said super-elastic material comprises a nickel-titanium alloy (col. 6, lines 59-60); wherein said at least one strand comprises a shape memory material; wherein said shape memory material comprises a nickel-titanium alloy (col. 6, lines 59-60); wherein the anchor portion is formed to reinforce the vessel in the vicinity of the damaged portion of the vasculature to be treated; the second operable configuration having an anchor segment further comprises at least one extending loop, the extending loop being curved about a longitudinal axis to form a hollow cylindrical circumferential pattern of loops about the longitudinal axis to provide a contact surface area to anchor the occluding portion of the device adjacent the artery system of the vasculature to be treated; wherein the second portion having a first inoperable, substantially linear configuration for insertion into and through a catheter to

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a desired portion of the vasculature to be treated, and a second operable configuration consisting of a coil segment further comprising, a coiled shape for filling and reinforcing the desired part of the vasculature when the vasoocclusive device is implanted at the site in the vasculature to be treated; the second portion having a first inoperable, substantially linear configuration for insertion into and through a catheter to a desired portion of the vasculature to be treated, and a and through a catheter to a desired portion of the vasculature to be treated, and a second operable, substantially spherical configuration for occluding at least a portion of said vasculature to be treated, said substantially spherical configuration having about 90% of said strand in about the outer 15% of the diameter of said substantially spherical configuration (see figures).





Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. M./  
Examiner, Art Unit 3734

/Darwin P. Erezol/  
Primary Examiner, Art Unit 3773